IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Yoshihiko HIGUCHI et al.

Serial No. 08/959,125

Filed October 28, 1997

DRY MEASURING TEST DEVICE

Mail Stop: APPEAL BRIEF-PATENTS

Confirmation No. 4244

Docket No. 2003-1789

Group Art Unit 1743

Examiner Lyle ALEXANDER

APPEAL BRIEF

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This is an appeal from the final decision of the Examiner set forth in the Office Action dated April 1, 2004, finally rejecting claims 2-5 and 14-16 which are attached herewith in the Claims Appendix. A Notice of Appeal was filed September 1, 2004.

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I. REAL PARTY IN INTEREST

The real party in interest is ARKRAY INC., assignee of the entire right, title and interest to this application.

II. RELATED PROCEEDINGS

There are no related prior nor pending appeals, interferences, or judicial proceedings known to Appellants, Appellants' legal representatives, or assignee which will affect or be affected by, or have a bearing on the Board's decision in the present appeal.

III. STATUS OF THE CLAIMS

The status of the claims as set forth in the final Office Action dated April 1, 2004 is as follows:

Claims pending:

2-16

Claims canceled:

1

Claims withdrawn:

6-13

Claims rejected:

2-5 and 14-16

Claims appealed:

2-5 and 14-16

IV. STATUS OF AMENDMENTS

The last amendment to the claims was in the response filed on December 23, 2003, which was considered and entered into the record by the Examiner in the final Office Action dated April 1, 2004.

V. SUMMARY OF THE CLAIMED INVENTION

A. Independent Claim 15

The invention of independent claim 15 is a dry measuring test device for detecting a substance in a liquid sample by measuring the degree of reaction between the substance to be

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measured and a chromogenic reagent in terms of units of light reflectance (specification, page 3, lines 19-25). The claimed dry measuring test device comprises a single reagent layer comprising a reagent, polymer beads, and a matrix (specification, page 4, lines 12-19).

The reagent contained in the reagent layer of the dry measuring test device comprises a chromogen. The chromogen can develop color by reacting with the substance to be measured in the liquid sample (specification, page 6, lines 10-20).

The polymer beads contain embedded light reflective particles (specification, page 4, lines 18-31 and page 7, lines 20-36).

The matrix comprises a hydrophilic high molecular substance and contains the reagent and the polymer beads (specification, page 4, lines 12-19 and page 10, lines 20-27).

The polymer beads are contained within (embedded) the matrix at content of 5 to 30 wt% of the total weight of the single reagent layer (specification, page 8, lines 12-22).

The substance to be measured is determined by measuring the degree of coloring of the chromogen generated through the reaction between the substance to be measured and the reagent in terms of reflectance of light entered into the reagent (specification, page 3, lines 19-25 and page 4, lines 15-19). The dry measuring test device achieves a short period of the measuring time and gives a sufficiently measurable reflectance corresponding to a low degree of coloring upon the measurement of reflectance, thereby, achieving a speedy and highly accurate measurement (specification, page 3, lines 19-33).

B. Dependent Claims 2-5 and 16

The invention of dependent claim 2-5 and 16 relate to the polymer beads containing embedded light reflective particles.

Specifically, the invention of dependent claim 2 relates to the different kinds of light reflective particles (specification, page 4, lines 20-24).

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The invention of dependent claim 3 relates to the specific main high molecular component

of the polymer beads of the dry measuring test device (specification, at page 4, lines 25-31, page 8,

lines 7-12).

The inventions of dependent claims 4 and 5 relate to the average pore diameter of the

polymer beads (specification, page 8, lines 23-24) and to the w/v% content of the light reflective

particles (specification, at page 8, lines 12-14).

The invention of dependent claim 16 relates to the polymer beads consisting of a polymer

and the light reflective particles (specification, at page 5, lines 36-38).

VI. LISTING OF REJECTION

Claims 2-5 and 14-16 are rejected under 35 U.S.C. § 103(a) as obvious over Siddiqi, U.S.

Patent No. 4,438,067.

VII. ARGUMENT

Claims 2-5 and 14-16 are rejected under 35 U.S.C. § 103(a) as obvious over Siddiqi, U.S.

Patent No. 4,438,067 for the reasons set forth on page 2 of the final Office Action of April 1, 2004.

Appellants respectfully traverse this rejection for the following reasons.

To establish obviousness, three criteria must be met. First, the prior art references must teach

or suggest each and every element of the claimed invention. Second, there must be some suggestion

or motivation in the references to either modify or combine the reference teachings to arrive at the

claimed invention. Third, the prior art must provide a reasonable expectation of success.

In the instant case, the claims are drawn to a dry measuring test device comprising a single

reagent layer comprising (i) a reagent containing a chromogen, (ii) polymer beads containing

embedded light reflective particles, and (iii) a matrix comprising a hydrophilic high molecular

substance. Moreover, the matrix contains the reagent and the polymer beads, wherein the content

of the polymer beads is 5 to 30 wt% of the total weight of the single reagent layer.

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Siddiq fails to disclose or suggest a dry measuring test device comprising <u>a matrix</u> containing the polymer beads wherein the content of the polymer beads is 5 to 30 wt% of the total weight of the single reagent layer. Siddiqi fails to disclose or suggest the claimed matrix. Nor does Siddiqi disclose or suggest the claimed content of the polymer beads.

The Examiner has stated that Applicants are arguing limitations not present in the claims by arguing that the polymer beads are naturally embedded in the matrix. Specifically, the Examiner has stated that the instant claims fail to recite that the polymer beads are embedded in the matrix as argued in the response filed on December 23, 2003 (page 5).

However, this position overlooks the claim limitation calling for a matrix containing the polymer beads. Siddiqi is silent about a matrix which contains the reagent according to the dry measuring test device of the present invention. In fact, Siddiqi teaches that beads are attached by adhesion to the supporting strip <u>without any matrix</u> for embedding the beads. The test strip of Siddiqi comprises a support and a layer of beads coated onto and bonded to a surface of the support to define pockets between mutually contacting beads in which the aqueous test solution can be retained. Specifically, Siddiqi described as follows:

"The beads are simply attached by adhesion to the supporting strip without any dispersive and absorbent matrix for embedding the beads like in the strips of the prior-art in which said matrix serves usually as a sampling medium for the solutions to be tested and also as a development medium for the desired color analytical reaction." (Emphasis added; col. 3, line 65 to col. 4, line 3).

Siddiqi clearly teaches that beads are attached by adhesion to the supporting strip without any matrix for embedding the beads. As such, Siddiqi <u>teaches away</u> from retaining beads in the matrix. Accordingly, one skilled in the art would not have been motivated to modify the strip of Siddiqi along the lines of the claimed invention.

Furthermore, Siddiqi fails to disclose or suggest that the claimed <u>5 to 30 wt% content of the</u>

polymer beads to the total weight of the single reagent layer. At this content, the amount of the

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matrix is much larger than that of the polymer beads in the reagent layer. Also, as discussed in the response filed on August 2, 2004 (page 2) and the response filed December 23, 2003 (page 5), the polymer beads are retained in the matrix. That is, the polymer beads are retained (i.e. embedded) in the matrix at content of 5 to 30 wt% of the total weight of the single reagent layer as described in the specification, page 8, lines 12-22. The claimed content of the polymer beads in claim 15 emphasizes this feature.

Please see lines 4-34 on page 10 and lines 9-10 on page 16 of the specification wherein it is disclosed that the procedures for preparing the matrix result in the polymer beads being contained and retained in the matrix (i.e., embedded in the matrix).

Siddiqi fails to disclose or suggest this content. Instead, the Examiner has stated that it would have been within the skill in the art to modify Siddiqi and select a content of polymer beads being 5-30 wt.% of the total reagent layer. However, the dry measuring test device of this invention is not achieved by optimization of that disclosed by Siddiqi. There is simply no suggestion or motivation to select a content of polymer beads being 5-30 wt.% of the total reagent layer.

Moreover, in the test strip of Siddiqi, the beads are not embedded in the matrix. Contrary to the Examiner's position, the pressing of the beads into the adhesive on the surface as taught by Siddiqi does not result in the reagent layer wherein the content of the polymer beads is 5 to 30 wt% of the total weight of the single reagent layer.

Indeed, Siddiqi describes that "a very thin layer of the adhesive solution can be sprayed or otherwise deposited on the latter" (column 6, lines 16-18 of Siddiqi) [Emphasis added]. However, in the layer of Siddiqi, it is clear that the beads occupy almost the whole layer in terms of both volume and weight. In this regard, Siddiqi clearly teaches away from the claimed contents of the polymer beads.

Also, with respect to claim 16, the Examiner contends that Siddiqi at column 5, lines 20+ teaches titanium dioxide incorporated within the beads, thus allegedly satisfying the "polymer beads containing embedded light reflective particles." However, in Siddiqi, the beads must contain

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analytical reagents (column 4, lines 55-57). Siddiqi does not teach beads consisting of a polymer and light reflective particles.

In sum, it is clear that Siddiqi fails to disclose or suggest the use of matrix containing polymer beads. Siddiqi also fails to disclose or suggest the claimed content of the polymer beads. Also, since Siddiqi actually teaches away from the use of a matrix, one skilled in the art would not have been motivated to modify the strip of Siddiqi along the lines of the claimed invention.

Thus, for the reasons set forth above, the rejection of claims 2-5 and 14-16 under 35 U.S.C. § 103(a) as obvious over Siddiqi is untenable and should be reversed.

VIII. CONCLUSION

For the foregoing reasons, claims 2-5 and 14-16 are novel and unobvious over the cited reference. Thus, reversal of the final rejection is respectfully requested.

Attached herewith are a Claims Appendix, an Evidence Appendix, and a Related Proceedings Appendix.

Respectfully submitted,

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CLAIMS APPENDIX:

1. (Canceled)

- **2.** (Appealed) The dry measuring test device as claimed in Claim 15, wherein said light reflective particles are selected from the group consisting of titanium dioxide, zinc oxide, barium sulfate, magnesium oxide, iron (III) oxide and iron (III) hydroxide.
- **3.** (Appealed) The dry measuring test device as claimed in Claim 15, wherein said polymer beads contain as a main component a high molecular compound selected from the group consisting of: polymer or copolymer having as a main component monomers selected from the group consisting of acrylic acid, methacrylic acid, maleic acid, ester of these substances, styrene, and alkylstyrene; polyurethane; polyurea; polyethylene; polypropylene; and polyvinyl chloride.
- 4. (Appealed) The dry measuring test device as claimed in Claim 15, wherein an average particle diameter of the polymer beads ranges from 1 to 40 μ m.
- **5.** (Appealed) The dry measuring test device as claimed in Claim 15, wherein the light reflective particles are contained in an amount of 10 to 70 w/v% based on the total content of the polymer beads.
- 6. (Withdrawn) A dry measuring test device, comprising a reagent layer comprising a reagent containing a chromogen and a matrix which retains said reagent in the form of a layer, for determining a substance to be measured in a liquid sample by measuring the degree of coloring of the chromogen generated through the reaction between the substance to be measured and the reagent in terms of reflectance of light entered into the reagent layer, wherein a light blocking layer containing light blocking particles is laminated on the reagent layer.

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7. (Withdrawn) The dry measuring test device as claimed in Claim 6, wherein the light

blocking particles are selected from the group consisting of carbon black, iron (II) oxide, iron (II)

iron (III) oxide, phthalocyanine blue, and phthalocyanine green.

8. (Withdrawn) The dry measuring test device as claimed in Claim 6, wherein the light

blocking particles are contained in an amount of 15 to 90 wt% based on the total weight of the light

blocking layer.

9. (Withdrawn) The dry measuring test device as claimed in Claim 6, wherein the light

blocking particles are contained in the light blocking layer in the form of polymer beads embedding

them.

10. (Withdrawn) The dry measuring test device as claimed in Claim 9, wherein the

polymer beads contain as main component a high molecular compound selected from the group

consisting of: polymer or copolymer having as the main component monomers selected from the

group consisting of acrylic acid, methacrylic acid, maleic acid, ester of these substances, styrene, and

alkylstyrene; polyurethane; polyurea; polyethylene; polypropylene; and polyvinyl chloride.

11. (Withdrawn) The dry measuring test device as claimed in Claim 9, wherein the light

blocking particles are contained in an amount of 10 to 70 w/v% based on the total content of the

polymer beads, and the polymer beads are contained in the light blocking layer in an amount of 30

to 90 wt% based on the total weight of the light blocking layer.

12. (Withdrawn) The dry measuring test device as claimed in Claim 9, wherein an average

particle diameter of the polymer beads ranges from 1 to 5 µm.

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13. (Withdrawn) The dry measuring test device as claimed in Claim 6, wherein the reagent

layer further contains the polymer beads embedding the light reflective particles.

14. (Appealed) The dry measuring test device as claimed in Claim 15, wherein the

hydrophilic high molecular substance is a substance selected from the group consisting of

hydroxypropylcellulose, methylcellulose, sodium alginate, polyvinyl alcohol, polyvinyl pyrrolidone,

gelatin, modified gelatin, agar, acrylamide polymer, and agarose.

15. (Appealed) A dry measuring test device for detecting a substance in a liquid sample by

measuring the degree of reaction between the substance to be measured and a chromogenic reagent

in units of reflectance of light, comprising a single reagent layer comprising (i) a reagent containing

a chromogen, (ii) polymer beads containing embedded light reflective particles, and (iii) a matrix

comprising a hydrophilic high molecular substance which matrix contains said reagent and said

polymer beads, wherein the content of the polymer beads is 5 to 30 wt% of the total weight of the

single reagent layer.

16. (Appealed) The dry measuring test device as claimed in Claim 15, wherein said polymer

beads containing embedded light reflective particles consist of a polymer and the light reflective

particles.

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EVIDENCE APPENDIX:

None

RELATED PROCEEDINGS APPENDIX:

None